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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,598	10/12/2004	Joseph P. Errico	SPINE 3.0-437	8307
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SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 05/31/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,598

Applicant(s)

ERRICO ET AL.

Examiner

BRIAN PELLEGRINO

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/15/10, 4/15/11
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/10 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the apparatus for repositioning an intervertebral implant having **a plurality of shafts** (defined by the recitation of "at least one shaft") with two pins coupled to the shaft distal end having one pin located on the longitudinal axis of the shaft and another second pin located offset to the longitudinal axis of the shaft must be shown or the feature(s) canceled from the claim(s). Additionally, the apparatus comprising **more than two prongs** (defined by the recitation of "at least one prong") must be shown or the features canceled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5,7,8,12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1,12 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble of claim 1, applicant recites "An apparatus" with the intervertebral implant being only functionally recited, i.e. "for

repositioning an intervertebral implant ...", thus indicating that the claim is directed to the subcombination, "An apparatus". However, in line 15 of claim 1, applicant positively recites "the implant includes at least two holes" as part of the invention, i.e. "the ...pins being sizedfor simultaneous engagement with at least two of the at least two holes", thus indicating that the combination, apparatus or tool and the implant, might be intended to be claimed. Regarding claim 12, Applicant recites "A set of apparatuses" with the intervertebral implant being only functionally recited, i.e. "for repositioning an intervertebral implant ...", thus indicating that the claim is directed to the subcombination, "A set of apparatuses". However, in line 14 of claim 12, applicant positively recites "the implant includes multiple pairs of holes" as part of the invention, i.e. "each hole pair is engageable by any of the pairs of pins", thus indicating that the combination, apparatus or tool and the implant, might be intended to be claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to amend to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent.

Claim 1 also recites the limitation "at least one shaft" in line 4 of the claim. However, in lines 7,8,12,14,20 of the claim only one shaft is claimed by recitation of "the shaft". Thus there is ambiguity as to if Applicant intended there to be more than one shaft or just one. Clarification is required. Applicant is reminded to direct claims to the elected embodiment which shows one shaft.

Claim 1 recites the limitation "the at least two pins" in line 16 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 2,4,14 are rejected under 35 U.S.C. 112, fourth (4th) paragraph, as being an improper dependent claim for failing to further limit the subject matter of the claim upon which it depends. Specifically claim 2 requires "the implant is a spacer, an artificial intervertebral disc or an artificial intervertebral disc trial" which depends from claim 1 of which claims (An apparatus) i.e. the shaft with pins. Specifically claim 4 requires "engagement.....enables extraction....via **application of a force** to the shaft..." which is an act in nature and thus does not further define the apparatus or can be claimed in product claims. Specifically claim 14 requires "**application of a pressure** to the shaft..." which is an act in nature and thus does not further define the apparatus or can be claimed in product claims.

Claim 12 is also indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the clause "respective orientation" is indefinite. It is not clear how to determine what one of ordinary skill might consider "respective orientation" as this lacks a frame of reference. The claim fails to set forth parameters that clearly define such an orientation. Additionally, claim 12 had established a definite or specific arrangement reciting "a pair of pins coupled to the shaft distal end and extending in a same direction parallel to one another and perpendicular to a plane passing through the longitudinal axis" but then recites "each apparatus has a respective orientation of the longitudinal axis of the shaft of the

apparatus relative to the orientation of the pair of pins of the apparatus.." that contradicts the specific arrangement already recited. This is ambiguous and confusing.

Claim 12 is also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: where the pins are in relationship to the prongs. Claim 12 recites "the distal end of the shaft including a first prong and a second prong" and then recites "a pair of pins coupled to the shaft distal end.." without clarification where these features are relative to one another. It is critical that recitation be included because both the pins and prongs are located at the distal end. Thus the claim must explain how.

Claims 3,5,7,8,13,15 are rejected to for being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,7,8,14,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Foster (1425845). Foster discloses (Fig. 2) apparatus having a shaft **A** with a distal end and a longitudinal axis with the distal end bending toward a left direction relative the axis of the shaft. It can be seen that there are two pins **a¹**,**b** coupled to the shaft distal end and being perpendicular to the longitudinal axis and parallel to each other.

Additionally it can be seen that pin **a**¹ is located on the longitudinal axis of the shaft and pin **b** is located offset from the longitudinal axis of the shaft. Additionally, it can be seen the apparatus is fully capable of engaging a "body" that has at least two holes illustrated by element **C** which has holes therein. Please note the intended use carries no weight in the absence of any distinguishing structure. Regarding claim 2, it can be seen element **C** is a disc. With respect to claim 3, the apparatus is fully capable of enabling rotation. Regarding claim 4, force is capable of being applied to the apparatus to extract an implant body. With respect to claim 5, an individual is capable of selecting holes to for a particular orientation of use. Regarding claim 7, Foster discloses the shaft end is lengthened and tapered forming a handle, col. 2, line 71. With respect to claim 8, it can be seen (Fig. 2) that Foster discloses a prong **B** to couple a pin to the shaft. With respect to claim 14, a perpendicular pressure is capable of being applied to the shaft of the apparatus. Regarding claim 15, it can be seen Foster shows (Fig. 2) the distal end of the shaft has a first straight prong (**a**) extending along the longitudinal axis and a second curved prong (**B**) extending away from the longitudinal axis in a left or right direction.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster '845 in view of Ripple et al. (4566466). Foster discloses the claimed invention except for a set of apparatuses. It is noted that Foster shows (Fig. 2) that an apparatus has a first straight prong (**a**) extending along the longitudinal axis and a second curved prong (**B**) extending away from the longitudinal axis. Foster additionally illustrates (Fig. 2) that there is a pair of pins **a**¹,**b** coupled to the shaft distal end and parallel with one another. Ripple et al. teach (Fig. 7) that apparatus or a tool for a specific procedure is provided in a set of apparatuses for the user. Ripple further teaches (col. 4, lines 38-47) that the set gives the user the ability to select a correct tool or instrument for the purpose of matching with the required dimension. It would have been obvious to one of ordinary skill in the art to provide a set of apparatuses by Foster using the teaching of Ripple et al. so that the user can have a tool or apparatus to engage with the body or implant element having holes to match appropriate dimensions. Because the individual components of applicant's claimed apparatus "for repositioning" set are known in the prior art, it would have been obvious to one of ordinary skill in the art at the time of the invention to have a plurality of these components available at the same time (i.e., as in a "set"), such as during a work procedure using the tool, so that the user can select the appropriately arranged and sized apparatus for the particular disc coupling with. Regarding claim 13, the apparatus is capable of being used in an anterior approach or an anterior-lateral approach.

Response to Arguments

Applicant's arguments with respect to claims 1-5,7,8,12-15 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN PELLEGRINO whose telephone number is (571)272-4756. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738